

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF NEW YORK

**WELCH ALLYN, INC.,**

*Plaintiff,*

-VS-

**OBP CORPORATION and OBP  
MEDICAL INC.,**

*Defendants.*

Civil Action No.  
5:14-cv-01122-TJM-DEP

**WELCH ALLYN, INC.'S OPENING CLAIM CONSTRUCTION BRIEF**

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Pursuant to the Uniform Pretrial Scheduling Order [*see* Dkt. 23], the plaintiff, Welch Allyn, Inc. (“Welch Allyn”), submits the following Opening Claim Construction Brief.

### **Background**

#### **A. The Present Dispute**

This is a patent infringement case between Welch Allyn (the patent owner) and OBP Corporation and OBP Medical, Inc. (collectively, “OBP”) (the infringer). The patent at issue is U.S. Patent No. 8,435,175 (the “’175 Patent”), which is attached to the accompanying Declaration of Douglas J. Nash, dated May 28, 2015, (“Nash Decl.”) as Exhibit A. Entitled “Vaginal Speculum Apparatus,” the ’175 Patent reflects a breakthrough in the design of vaginal specula that was the culmination of years of study by an inter-disciplinary team of Welch Allyn mechanical, electrical, and optical engineers.

Based in Skaneateles Falls, New York, Welch Allyn is a family-owned business that has been designing and manufacturing medical diagnostic equipment and patient monitoring systems in upstate New York since 1915. Employing nearly 2,600 people worldwide, including almost 1,000 people at its Skaneateles Falls facility, Welch Allyn is on the cutting edge of helping healthcare providers overcome complex challenges to providing services by engineering effective products that are elegantly designed. Welch Allyn’s innovations help doctors, nurses, and other healthcare providers (and ultimately, patients) by making products and solutions that enable healthcare providers to see more patients, perform more procedures, and provide better on-site care. In fact, ever since 1915 when Welch Allyn sold the world’s first hand-held, direct-illuminating ophthalmoscope that was developed by Dr. Francis Welch and William Noah Allyn, innovation has been at the very core of Welch Allyn’s business. (*See* Declaration of Tracy L. Bennett, dated May 28, 2015 (“Bennett Decl.”), ¶ 5.)

OBP is a small medical products company based in Lawrence, Massachusetts. Founded in 2006, OBP is believed to have just a handful of employees. It is further believed that OBP outsources the manufacturing of its products to Asia. Among those products are vaginal specula sold by OBP under the trade names ER-SPEC and OfficeSPEC. Both the ER-SPEC and OfficeSPEC products infringe certain of the claims in the '175 Patent. In fact, the products are such well-executed knock-offs of Welch Allyn's proprietary designs that, for some of its products, OBP has even copied the same trade dress that Welch Allyn uses in its commercial products. Welch Allyn believes that this was done intentionally by OBP to confuse customers and other end-users into thinking that the products are high-quality Welch Allyn products. Indeed, Welch Allyn has received technical support calls from multiple customers who thought they were using a Welch Allyn speculum, only to discover on the call that they were using an OBP speculum. Similarly, Welch Allyn employees have had a number of customers approach them at recent trade shows to discuss Welch Allyn's specula, only to learn during the course of the conversations that the customers were actually talking about OBP's specula. (*See id.*, ¶¶ 6-7.)

In an effort to try to resolve the dispute, OBP was put on notice of these issues before the Complaint in this case was served. Unfortunately, OBP stubbornly refused to stop its knowing and willful infringement of Welch Allyn's intellectual property rights, thus bringing the parties to the point in this case where the Court is now being asked to construe certain disputed terms in the asserted claims in the '175 Patent.

## **B. The Invention**

"Vaginal specula are . . . used in the field of diagnostic medicine for purposes of examining the cervix of a female patient. A typical vaginal speculum includes an upper blade member and a lower blade member that are operated upon to open and close by means of an

articulation mechanism in order to dilate the vaginal cavity of the patient.” (’175 Patent, col. 1, lines 28-34.) To effectively examine inside the vaginal cavity of a patient, a light source is often used in conjunction with vaginal specula to provide sufficient illumination of the examination area. (*See id.* at col. 1, lines 35-52.) However, medical practitioners have encountered significant difficulty in doing so effectively.

For example, some specula were used with an illumination assembly in which a light source was powered using a tethered power cable. However, “there are occasions in which such assemblies make examination impractical to perform such as, for example, instances in which the patient is bed-ridden. In these situations, the corded portion of the speculum apparatus can become an impediment to examining a patient. In addition, the use of corded illumination assemblies requires a non-portable (*e.g.*, AC) power supply to be present in the examination area, making field examinations difficult. Still further, corded assemblies can become tangled or become a source of dirt or other contamination, requiring frequent cleaning between examinations.” (*See id.* at col. 2, lines 17-29.)

In addition, light sources used with specula have caused so-called “hot” spots in which the light source “produces back reflection of light to the eye of the user . . . [which] produces considerable amounts of glare, thereby impairing the effectiveness of an examination.” (*See id.* at col. 1, lines 53-63.) Moreover, light sources positioned within the specula can extend “into the lower field of view of the user (*e.g.*, the physician), creating obstruction of the target.” (*See id.* at col. 1, lines 64-67.) Relatedly, “body fluids expelled from examination are often trapped by the [light source], producing a contamination issue as well as impairing the efficiency of examination given the effect on light transmission of a buildup of fluids against the light-emitting surface of the light pipe.” (*See id.* at col. 2, lines 11-16.)

In 2002, an inter-disciplinary team of Welch Allyn mechanical, electrical, and optical engineers started to work on various solutions to the problems associated with illuminated vaginal specula. At that time, LEDs typically were not used as illumination sources in medical products, including vaginal specula. In fact, “the incorporation of such light sources in portable illumination systems for vaginal specula [had] been discouraged in the field due to inefficiencies in power conversion and illumination output,” and were “presently unavailable for use in such apparatus.” (*See id.* at col. 2, lines 30-38.) Despite this, the Welch Allyn team explored a number of designs using LED technology. (*See* Declaration of Scott G. Spanfelner, dated May 28, 2015 (“Spanfelner Decl.”), ¶ 9.)

Among the novel ideas conceived by Welch Allyn was the use of a disposable cartridge that included an LED and batteries and was located either in the upper or lower blade of the speculum. The cartridge could be removable and would either turn on automatically when inserted into one of the blades, or it could be turned on using a switch, such as a pull out activation tab. Welch Allyn also conceived using a removable light pipe or prism that could be used to transmit light from an LED to the examination area of the patient. Contemporaneous documents and records kept by Welch Allyn in the ordinary course of its business (and produced to OBP during discovery in this case) evidence the fact that these ideas were conceived and reduced to practice no later than August 29, 2002, by which time a working prototype embodying these ideas had been constructed. (*See id.* at ¶ 10.)

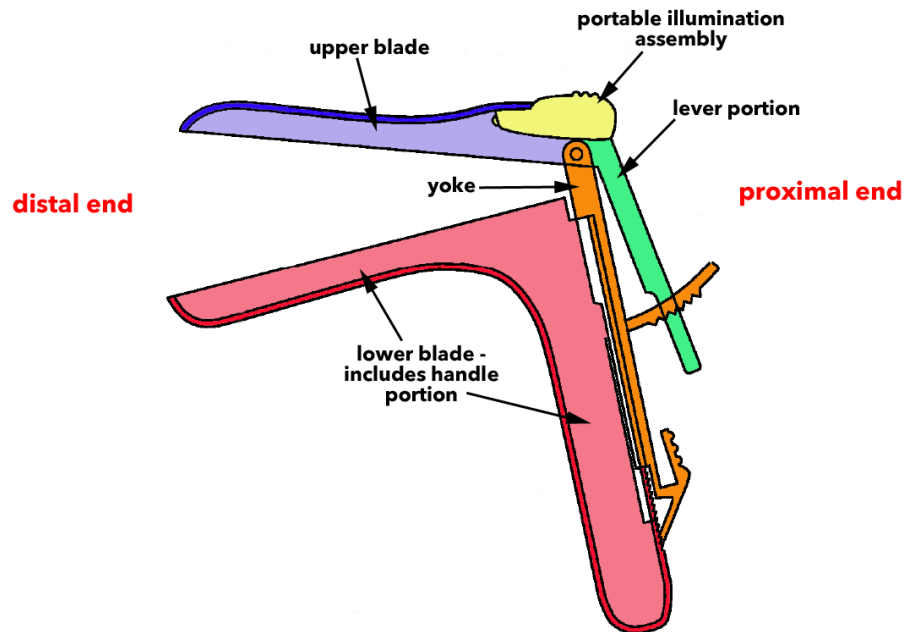
These ideas are disclosed in detail in the '175 Patent, including, among other places, Figures 23, 24, and 35, and the specification's accompanying discussion of those figures. These ideas represented a true breakthrough in the design of vaginal specula. For the first time, it was understood how to make a fully disposable illuminated vaginal speculum without a tethered



power cord that also helped reduce “hot” spots, obstructed views, and contamination of the light source – all while utilizing LED technology that, prior to the invention disclosed in the ’175 Patent, was thought to be unsuitable for use in vaginal specula. (*See id.* at ¶ 11.)

### C. The Anatomy of a Speculum

Below is an annotated version of Figure 35 from the ’175 Patent, which identifies a number of specula components and reference points. For example, the figure identifies, as reference points, the distal and proximal ends of the speculum. It also indicates that, as expressly taught in the ’175 Patent, the lower blade includes both a trough-shaped portion and a handle portion, and identifies the lever portion and the yoke, which together form an opening for a practitioner to look through to examine a patient and are configured to allow the blades to open and close to help dilate the patient. The figure also identifies an example of where, within either the upper or lower blades, a portable illumination assembly could be inserted and accessed through the opening formed by the lever portion and the yoke.



#### **D. Legal Standard**

The purpose of claim construction is to resolve “disputed meanings and technical scope, to clarify and when necessary to explain what the patentee covered by the claims, for use in the determination of infringement.” *See U.S. Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554, 1568 (Fed. Cir. 1997). However, “Courts do not rewrite claims; instead, we give effect to the terms chosen by the patentee.” *K-2 Corp. v. Salomon S.A.*, 191 F.3d 1356, 1364 (Fed. Cir. 1999). Claim construction is to be performed by a court as a matter of law. *See Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372 (1996).

In performing this function, courts are mindful of the “bedrock principle” of patent law that it is the language in the claims, not the specification or the prosecution history, that defines the scope of the invention. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc); *see also Arlington Indus. v. Bridgeport Fittings, Inc.*, 632 F.3d 1246, 1253 (Fed. Cir. 2011) (reversing district court’s claim construction because it violated the “bedrock” principle that it is the language in the claims that defines the scope of the invention).

While claims are read in light of the patent’s specification, which along with the prosecution history can be useful tools in understanding the invention, it is the “cardinal sin” of claim construction to limit the scope of the claims based on the examples in the specification. *See, e.g., Kara Tech. Inc. v. Stamps.com Inc.*, 582 F.3d 1341, 1348 (Fed. Cir. 2009) (“The patentee is entitled to the full scope of his claims, and we will not limit him to his preferred embodiment or import a limitation from the specification into the claims.”); *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1324-28 (Fed. Cir. 2002) (discussing the importation of limitations from the written description into the claims as the “cardinal sin” of claim construction); *Xerox Corp. v. Media Scis., Inc.*, 694 F. Supp. 2d 304, 318 (S.D.N.Y. 2010)

(attempting to “to read a limitation from a preferred embodiment” into a claim “is one of the cardinal sins of claim construction”).

The terms in the claims are given their plain, ordinary, and customary meaning as they would have been understood by a person of ordinary skill in the art. *See Phillips*, 415 F.3d at 1313. However, there are two primary exceptions to this general rule: (i) when a patentee, acting as its own lexicographer, sets out an explicit definition for a claim term in the patent that differs from the ordinary meaning; or (ii) when the patentee clearly and unambiguously disavows the full scope of a claim term either in the specification or during prosecution. *See Thorner v. Sony Computer Entm’t Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012); *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). To act as its own lexicographer, a patentee must “clearly set forth a definition of the disputed claim term” other than its plain and ordinary meaning. *See CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002). It is not enough for a patentee to simply disclose a single embodiment or use a word or figures in the same manner in all embodiments. *See Helmsderfer v. Bobrick Washroom Equip., Inc.*, 527 F.3d 1379, 1381 (Fed. Cir. 2008). The patentee must “clearly express an intent” to redefine the term. *See id.*

The standard for disavowal of claim scope is similarly exacting. “Absent a clear disavowal in the specification or the prosecution history, the patentee is entitled to the full scope of its claim language.” *Home Diagnostics, Inc. v. LifeScan, Inc.*, 381 F.3d 1352, 1358 (Fed. Cir. 2004). As the Federal Circuit has held repeatedly, it is “not enough that the only embodiments, or all of the embodiments, contain a particular limitation. We do not read limitations from the specification into claims; we do not redefine words. Only the patentee can do that.” *See, e.g., Thorner*, 669 F.3d at 1366. Stated another way, “[t]he patentee is free to choose a broad term

and expect to obtain the full scope of its plain and ordinary meaning unless the patentee explicitly redefines the term or disavows its full scope.” *See id.* at 1367.

### **Argument**

The asserted claims in this case are Claims 1-4, 6-9, 11-15, and 18-19 of the '175 Patent. As set forth in the Joint Claim Construction Statement (“JCCS”) [Dkt. 36] and pursuant to the Local Patent Rules, the parties have narrowed the disputed claim construction issues in this case to fewer than ten related terms/phrases.<sup>1</sup>

#### **I. “switch” and “mechanism for energizing”**

Claim Term/Phrase	Proper Construction
“switch”  (Claims 4, 15, 19)	Structure that can be acted upon to energize the LED
“mechanism for energizing”  (Claims 3, 9, 18)	Structure that can energize the LED

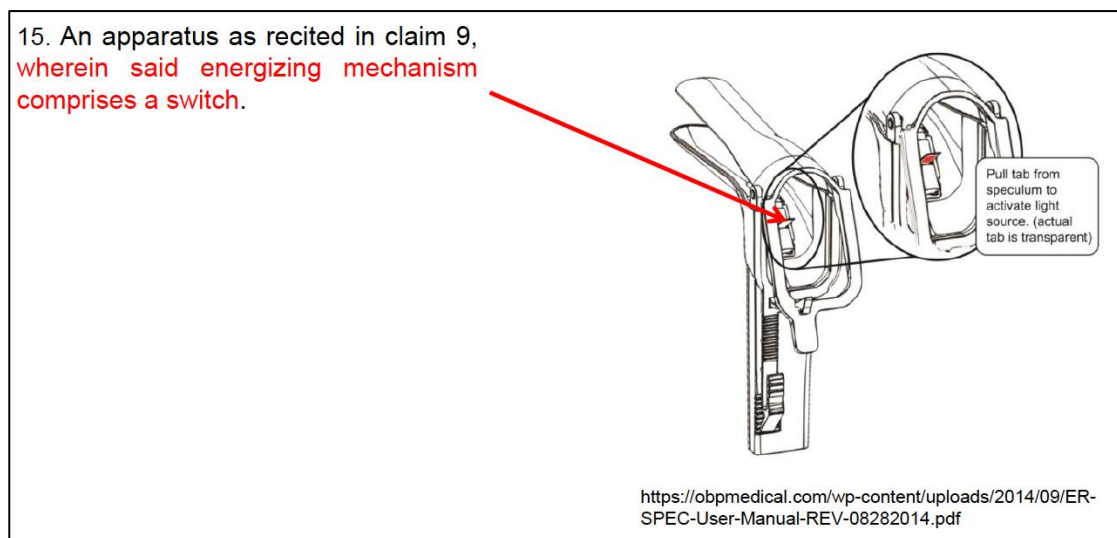
Claims 3, 9, and 18 require the claimed specula to have a “mechanism for energizing” the LED used in the portable illumination assembly. Claims 4, 15, and 19 add the further limitation that the mechanism include a “switch.” While ordinarily these well understood terms would not be controversial, OBP’s infringing products use a pull-tab switch to energize the LED. Despite

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<sup>1</sup> The parties have agreed that the Court should construe the following terms as set forth herein: (i) “integral curved light pipe” in Claim 1 should be construed as “a component of the portable illumination assembly that transmits light”; (ii) “receives” in Claim 1 should be construed as “the handle portion itself (not some other component) holds or contains a portion of the portable illumination assembly”; (iii) “set of rails” in Claim 6 should be construed as “a pair of substantially straight structures (for example, a track) on the handle portion that aligns and retains a portion of the portable illumination assembly”; (iv) “housing” in Claim 1 should be construed as “an enclosure that retains the portable power supply”; and (v) “within a common housing” in Claims 9 and 18 should be construed as “an enclosure that retains within it the components of the portable illumination assembly.” (*See* JCCS, pp. 6, 10-11; E-mail to OBP dated April 14, 2015, Nash Decl., Ex. C; Letter from OBP dated April 17, 2015, p. 1, ¶ 4, Nash Decl., Ex. D.)

the fact that it is beyond dispute that the pull-tab switch is what is acted upon to energize the LEDs in the infringing products, OBP nonetheless contends that a pull-tab switch is neither “a mechanism for energizing” nor a “switch.” (*See* Non-Infringement and Invalidity Contentions, Exhibit A, pp. 8-9, Exhibit B, pp. 2, 11, 13, 19, Nash Decl., Ex. E.)

This is illustrated in more detail in the figure below. As can be seen, OBP uses a switch that includes a non-conductive tab that is positioned within a circuit to prevent the flow of electricity. The tab can be removed by pulling it out of the assembly, thereby completing the circuit and allowing electricity to flow.



(*See, e.g.*, Infringement Contentions, Chart, p. 20, Nash Decl., Ex. F.) This type of switch is unquestionably within the scope of the claimed invention. For one thing, the claims are not limited to a particular type of switch or mechanism. *See, e.g., Thorner*, 669 F.3d at 1367 (“The patentee is free to choose a broad term and expect to obtain the full scope of its plain and ordinary meaning unless the patentee explicitly redefines the term or disavows its full scope.”). Moreover, the specification expressly teaches that the claimed invention is **not** limited to a particular type of switch or mechanism for energizing the LED, making clear that, in addition to the exemplary switches depicted in the drawings:

[O]ther forms of switch assemblies, such as, **but not limited to** optical switches, magnetic/reed switches, and **other mechanical switches** (such as an ON/OFF throw switch that can be enabled with the speculum when engaged therewith to automatically or manually energize and de-energize the contained LED) can be utilized.

(’175 Patent, col. 12, lines 34-40 (emphasis added); *see* col. 21, lines 5-12; *see also* col. 2, lines 59-60.)

Yet, in an effort to manufacture a non-infringement defense where none exists, OBP asks the Court to limit the term “a mechanism for energizing” to specific examples given in the specification. This ignores not only the explicit teaching that any type of mechanism can be used to energize the LED, but it also is a blatant attempt to import limitations from the specification into the claims, which is known as the “cardinal sin” of claim construction. *See, e.g., Kara Tech.*, 582 F.3d at 1348 (“The patentee is entitled to the full scope of his claims, and we will not limit him to his preferred embodiment or import a limitation from the specification into the claims.”); *Teleflex*, 299 F.3d at 1324-28 (discussing the importation of limitations from the written description into the claims as the “cardinal sin” of claim construction); *Xerox*, 694 F. Supp. 2d at 318 (attempting to “to read a limitation from a preferred embodiment” into a claim “is one of the cardinal sins of claim construction”). The patent makes clear that a “mechanism for energizing” the LED can be any type of structure that can energize the LED, and that is how the Court should construe the term.

With respect to the term “switch,” OBP purports to take the position that no construction is necessary. Yet, as noted above, OBP clearly has a construction of that term in mind that excludes pull-tab switches. (*See* Non-Infringement Contentions, Exhibit A, pp. 8-9, Exhibit B, pp. 2, 11, 13, 19, Nash Decl., Ex. E.) Thus, where, as here, the parties have a dispute over the scope of a claim term, it is the Court’s responsibility to resolve that dispute lest the parties be permitted to argue claim construction, which is a question of law, to the jury. *See, e.g.,*

*O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1361-62 (Fed. Cir. 2008) (reversing district court's decision not to construe disputed term because it left the parties free to argue claim construction to the jury); *Every Penny Counts, Inc. v. American Express Co.*, 563 F.3d 1378, 1383 (Fed. Cir. 2009) (“[T]he court’s obligation is to ensure that questions of the scope of the patent claims are not left to the jury. In order to fulfill this obligation, the court must see to it that disputes concerning the scope of the patent claims are fully resolved.”); *PPC Broadband, Inc. v. Corning Optical Commc’ns RF, LLC*, No. 5:12-cv-911 (GLS/DEP), 2014 U.S. Dist. LEXIS 119226, \*4 (N.D.N.Y. Aug. 21, 2014) (“When faced with ‘an actual dispute regarding the proper scope’ of a patent claim, the court must construe the allegedly infringed claim to determine its meaning and scope.”).

As discussed above, the patent is clear that a “switch” can be any type of structure (including a pull-tab switch and “and other mechanical switches”) that can be acted upon to energize the LED. This construction is consistent with the ordinary and customary meaning of the term and should be adopted by the Court to resolve the parties’ dispute. (*See, e.g.*, <http://www.merriam-webster.com/dictionary/switch> (defining switch to mean “a device for making, breaking, or changing the connections in an electrical circuit”), Nash Decl., Ex. G; <http://dictionary.reference.com/browse/switch> (defining switch to mean “a device for turning on or off or directing an electric current or for making or breaking a circuit”), Nash Decl., Ex. G; Welch Allyn KleenSpec Single Use LED Vaginal Specula Brochure (depicting a disposable speculum with a pull tab-switch and instructing users to “simply pull switch when ready” to energize the LED light source), Nash Decl., Ex. H); *see, e.g., Phillips*, 415 F.3d at 1313 (the terms in the claims are given their plain, ordinary, and customary meaning as they would have been understood by a person of ordinary skill in the art).

## II. “said speculum is disposable” and “the entire apparatus is disposable”

Claim Term/Phrase	Proper Construction
“said speculum is disposable” ( <i>Claims 7, 11</i> )	The speculum is designed to be discarded after a single use or a single patient use
“the entire apparatus is disposable” ( <i>Claims 8, 12</i> )	The entire apparatus is designed to be discarded after a single use or a single patient use

Claims 7 and 11 require that “said speculum is disposable,” whereas Claims 8 and 12 add the limitation that “the entire apparatus is disposable.” The claims are clear on their face. When the claims require “said speculum is disposable,” they mean that at least the speculum is designed to be discarded after a single use or a single patient use. In contrast, when the claims require “the entire apparatus is disposable,” they mean that the entire apparatus (including the portable illumination assembly) is designed to be discarded after a single use or a single patient use. That is how the Court should construe these terms. *See, e.g., Aro Mfg. Co. v. Convertible Top Replacement Co.*, 365 U.S. 336, 339 (1961) (“the claims made in the patent are **the sole measure of the grant**”) (emphasis added); *Chimie v. PPG Indus.*, 402 F.3d 1371, 1377 (Fed. Cir. 2005) (“Claim construction begins with the intrinsic evidence of record, looking first to the claim language itself to define the scope of the patented invention” and only if “the claim language itself lacks sufficient clarity to ascertain the scope of the claims, [do] we look to the written description for guidance”); *accord In re Hiniker Co.*, 150 F.3d 1362, 1369 (Fed. Cir. 1998) (“[T]he name of the game is the claim.”)

These constructions are in accord with the specification, which teaches that the term disposable is used to refer to a single-use device, and that just the speculum can be disposable, or, alternatively, the entire apparatus, including the portable illumination assembly can be



disposable.<sup>2</sup> (*See, e.g.*, '175 Patent, col. 1, lines 20-24 (“This application generally relates to the field of hand-held medical diagnostic instruments, and more particularly to a vaginal speculum apparatus including a single-use or single patient speculum that distributes illumination from at least one illumination assembly attached to the speculum.”) (emphasis added); col. 4, lines 35-37 (“According to one version, the speculum is disposable, [a]lternatively, the entire apparatus, including the illumination assembly, is disposable.”) (emphasis added); col. 24, lines 44-46 (“Alternatively, the speculum 710 and illumination assembly 704 can each be discarded following single or single patient use.”) (emphasis added); col. 29, lines 40-44 (“the illumination assembly discussed with regard to each of the embodiments can be either a disposable version or, as described by a number of embodiments herein, a reusable assembly that can be attached to a disposable speculum.”) (emphasis added).)

OBP’s construction would import into the claims a series of limitations that simply are not there – *i.e.*, limiting the claimed specula to “three parts being made of molded plastic such as acrylic or polystyrene,” which are further “made of fewer parts and less expensive material than its reusable counterpart,” and “that can be disposed of in a standard waste disposal facility with an overall end user cost that is competitive with a multiple use counterpart.” Those limitations are nowhere in the claims, the specification, or the prosecution history of the '175 Patent. OBP has literally made them up out of whole cloth. They should be rejected, and the Court should construe the terms as Welch Allyn has proposed. *See Arlington Indus., Inc.*, 632 F.3d at 1253 (reversing district court’s claim construction because it violated the “bedrock” principle that it is

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<sup>2</sup> OBP describes its infringing ER-SPEC as a “[d]isposable, single-use device,” suggesting that OBP similarly understands the term “disposable” to refer to a product designed for a single-use. (*See* OBP-Medical-ER-SPEC-Product-Brochure.pdf, p. 2, Nash Decl., Ex. I.)

the language in the claims that defines the scope of the invention); *K-2 Corp.*, 191 F.3d at 1364 (“Courts do not rewrite claims; instead, we give effect to the terms chosen by the patentee.”).

**III. “said illumination assembly is accessed . . . through said opening” and “can be accessed . . . only through said defined opening”**

Claim Term/Phrase	Proper Construction
“said illumination assembly is accessed . . . through said opening”  ( <i>Claim 9</i> )	The portable illumination assembly can be energized and removed through the opening
“can be accessed . . . only through said defined opening”  ( <i>Claim 18</i> )	The portable illumination assembly is designed to be energized by accessing the energization mechanism through the opening formed by the shape of the yoke and the lever portion

Claim 9 requires that the portable “illumination assembly is accessed for at least one of energization of said at least one LED and removal through said opening.” The opening is described by the claim as being defined by the lever portion of the upper blade.<sup>3</sup> Thus, the speculum has to be configured so that a user can access the portable illumination assembly to either energize it or remove it through the opening. That is, the claim requires that the portable illumination assembly can be energized and/or removed through the opening, which is how the Court should construe this term.

Claim 18 similarly requires that “the energization mechanism can be accessed for energizing said at least one LED only through said opening.” The claim describes the opening as being formed by the downward lever portion of the upper blade and the yoke or fork shaped attachment. Claim 18, therefore, requires that the portable illumination assembly is designed to be energized by accessing the energization mechanism through the opening at the proximal end

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<sup>3</sup> An example of such an opening, as well as the opening discussed below in the context of Claim 18, is depicted in Figure 28 in the ’175 Patent, in which the lever portion is item 324, and the yoke is item 332.

of the speculum formed by the shape of the yoke and the lever portion, which is how the Court should construe this term.

These proposed constructions are consistent with the specification in the '175 Patent, which teaches that:

The speculum can include at least one feature, such as at least one opening, enabling user access to the LED energizing means, even while the illumination assembly is inserted within the speculum, enabling the illumination assembly to be selectively de-energized without requiring removal.

('175 Patent, col. 4, lines 9-14.) One example of such an embodiment is depicted in Figure 35 in the '175 Patent. In that figure, the portable illumination assembly is inserted and removed through the opening formed by the lever portion and/or the yoke, and the assembly is therefore said to be “releasably attached to the top blade 512 according to this embodiment although the housing can be alternatively positioned relative to either the top blade or the lower blade 516 of the speculum 510.” (*See id.*, col. 23, lines 14-16.)

For its part, OBP contends with respect to Claim 9 that the term at issue renders the claim indefinite. (JCCS, Exhibit A, p. 4.) However, OBP has not fully explained the basis for its contention. Because OBP bears the burden of proof on indefiniteness, Welch Allyn will respond to OBP's contention in its Responsive Claim Construction Brief once it understands exactly what argument is being advanced. With respect to Claim 18, the parties are largely in agreement on the proper construction. The one substantive area of disagreement appears to be OBP's contention that it needs to be “impossible” to access the energization mechanism except through the opening. The claim language does not require such an extreme and inflexible construction, and there is nothing in the specification that would support that type of limitation. Instead, the claim merely requires that the portable illumination assembly be designed to be energized by accessing the energization mechanism through the opening. That some other way to access it

may be possible is not controlling. What is controlling is how the speculum is designed to work, and that it is designed so that the illumination assembly is supposed to be accessed only through the opening. *See Apple Computer, Inc. v. Articulate Sys., Inc.*, 234 F.3d 14, 25 (Fed. Cir. 2000) (“the claim must be interpreted in light of the written description and the purpose of the invention”); *Kenall Mfg. Co. v. H.E. Williams, Inc.*, No. 09 C 1284, 2013 U.S. Dist. LEXIS 13724, \*6 (N.D. Ill. Feb. 1, 2013) (“hyper-technical readings of patents are to be avoided where they would arrive at an absurd result rather than achieve a common sense meaning”); *P & G Co. v. Paragon Trade Brands, Inc.*, 989 F. Supp. 547, 565 (D. Del. 1997) (rejecting defendant’s added condition of “impossible” as unsupported). The Court should, therefore, reject OBP’s construction for Claim 18 and adopt the construction proposed by Welch Allyn.

#### IV. “lower blade,” “handle portion” and “proximal end”

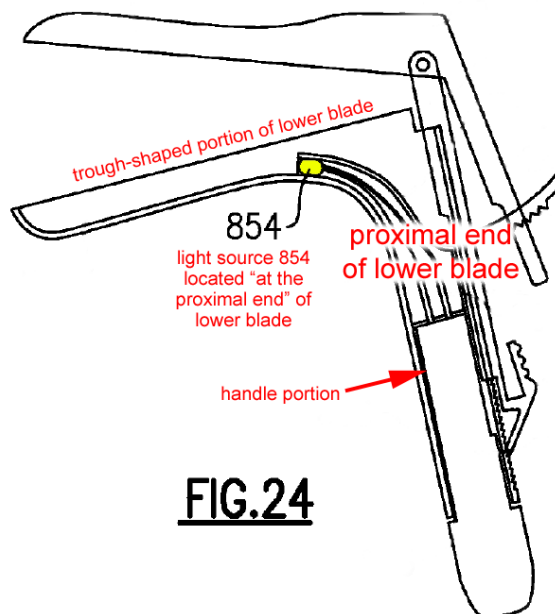
Claim Term/Phrase	Proper Construction
“lower blade”  ( <i>Claims 1, 9, 18</i> )	The blade that includes the handle portion
“handle portion”  ( <i>Claims 1, 14</i> )	A portion of the lower blade, at least part of which, is designed to be held in a user’s hand
“proximal end” (of the lower blade)  ( <i>Claims 9, 18</i> )	The portion of the lower blade closer to the rear of the lower blade (i.e., closer to the user) than the front of the lower blade (i.e., closer to the examination area)

All of the asserted claims require the claimed specula to have a “lower blade,” which both the claims and the specification make clear includes both a trough-shaped portion and a handle portion that is configured to be held in a user’s hand during a patient examination. (*See, e.g.,* ’175 Patent, Claim 1 (“said lower blade including a trough-shaped blade section and a handle portion”); col. 2, lines 42-50 (“said lower blade including a handle portion”); col. 22,

line 67; col. 23, lines 1-2 (“a lower blade 516 having a downwardly depending handle portion 520”); *see also* col. 7, lines 3-6; col. 16, lines 54-56; col. 19, lines 3-11; col. 21, lines 48-54; col. 24, lines 19-20.) Claim 9 requires that the portable illumination assembly be “entirely contained within the proximal end” of either the upper or lower blade. For the purpose of this case, the focus of the parties is on the lower blade, which is where the portable illumination assembly in OBP’s infringing products is located. Thus, as it relates to the lower blade, and as illustrated in the annotated version of Figure 35 that appears on page 5 above, the proximal end of the lower blade is the portion of the lower blade closer to the rear of the lower blade (*i.e.*, closer to the user) than the front of the lower blade (*i.e.*, closer to the examination area). This is consistent with how the specification uses the term proximal end. (*See, e.g.*, ’175 Patent, col. 7, lines 3-6 (referring to “the proximal or rear end of the lower blade member 104”); col. 23, lines 41-43 (“The top and lower blades 612, 614 define a proximal viewing aperture 630 therebetween for the user”); col. 23, lines 45-46 (referring to “the proximal (rearward) end”).)

Claim 14 adds a further limitation to the requirements set forth in Claim 9 that “at least a portion of said illumination assembly extends outside a handle portion thereof.” OBP has argued that Claim 14 is invalid because the illumination assembly cannot simultaneously be entirely contained within the proximal end” of the lower blade (Claim 9), and extend at least partially “outside a handle portion” of the lower blade. (*See Non-Infringement and Invalidity Contentions*, p. 32, Nash Decl., Ex. E.) Notwithstanding OBP’s position in the JCCS that none of these terms require construction, its invalidity argument concerning Claim 14 turns on a proper construction, thus necessitating a construction by the Court to resolve the dispute between the parties on what is a question of law. *See, e.g., O2 Micro*, 521 F.3d at 1361-62; *Every Penny Counts*, 563 F.3d at 1383; *PPC Broadband*, 2014 U.S. Dist. LEXIS 119226, at \*4.

What OBP's invalidity argument ignores is that the lower blade includes both a trough-shaped portion and a handle portion. The proximal end of the lower blade, which is the end nearest the user, necessarily is comprised of the handle portion (which is the portion closest to the user), but also includes part of the trough-shaped portion. The specification explicitly teaches this with respect to the exemplary embodiment shown in Figure 24. In that embodiment, the light source 854, which is positioned some distance inside the "trough-shaped" portion of the lower blade, is said to be located "at the proximal end" of the lower blade. (*See* '175 Patent, col. 25, lines 1-19; *see also* col. 7, lines 3-6 ("A handle portion 120 extends vertically downward from the proximal or rear end of the lower blade member 104, wherein the handle portion is integrally molded as part of the lower blade member.").) An annotated version of the Figure 24 embodiment is shown below to further illustrate this point.



Thus, when properly construed, Claim 14 and Claim 9 are not in conflict with one another. The portable illumination assembly can, in fact, simultaneously be contained entirely within the proximal end of the lower blade (Claim 9), and extend at least partially "outside a

handle portion” of the lower blade (Claim 14). For example, most of the illumination assembly could be positioned within the handle portion, with the remainder of the assembly extending into the trough-shaped section similar to what is shown in Figure 24. Both assembly portions in this example would be located at the proximal end of the lower blade. Another example would be where the illumination assembly was located entirely within the trough-shaped section, such as what might occur if the illumination assembly depicted in the Figure 35 embodiment were in the lower blade instead of the upper blade. (*See* ’175 Patent, col. 23, lines 15-16 (the illumination assembly in Figure 35 “can be alternatively positioned relative to either the top blade or the lower blade”).) In both examples, which are fully taught by the specification, “at least a portion” of the illumination assembly would extend outside the handle portion of the lower blade as required by Claim 14, while at the same time being “entirely contained within the proximal end” of the lower blade as required by Claim 9.

Accordingly, and to resolve the dispute between the parties, the term “lower blade” should be construed as “the blade that includes the handle portion,” the term “handle portion” should be construed as “a portion of the lower blade, at least part of which, is designed to be held in a user’s hand,” and the term “proximal end” of the lower blade should be construed as “the portion of the lower blade closer to the rear of the lower blade (*i.e.*, closer to the user) than the front of the lower blade (*i.e.*, closer to the examination area).” *See Whittaker Corp. v. UNR Indus.*, 911 F.2d 709, 713 (Fed. Cir. 1990) (“claims are generally construed so as to sustain their validity, if possible”).

#### V. **“releasably attached”**

Claim Term/Phrase	Proper Construction
“releasably attached”  ( <i>Claims 1, 9</i> )	Able to be detached

Claims 1 and 9 require that the portable illumination assembly be “releasably attached” to the handle portion of the lower blade in the case of Claim 1, or either the lower or upper blade in the case of Claim 9. The specification of the ’175 Patent teaches that “[i]n at least one version, the light pipe is releasably attached to the speculum,” while “[i]n another version, the light pipe can be integral to the lower blade of the speculum.” (’175 Patent, col. 3, lines 31-33; *see* col. 5, lines 3-4.) The specification further teaches that, in one exemplary embodiment:

The housing 508 is **releasably attached** to the top blade 512 according to this embodiment although the housing can be alternatively positioned relative to either the top blade or the lower blade 516 of the speculum 510, as discussed herein. Clips, fasteners or other conventional means **can be used to releasably attach** the housing 508 to the blade 512, wherein the illumination assembly 504 can also be used separately as an examination light **when detached**.

(’175 Patent, col. 23, lines 13-21 (emphasis added).) Thus, consistent with the ordinary and customary meaning of the phrase, when the claims require that the portable illumination assembly be “releasably attached” to one of the blades, they clearly mean that the portable illumination assembly is not integral to the blade and, instead, is able to be detached from the blade. That is how the Court should construe the term.

OBP, however, wants the Court to import limitations into the claims, impermissibly converting an easily understood two-word phrase into a twenty-three word missive that bears little to no relationship to the actual claim language. *See, e.g., Kara Tech.*, 582 F.3d at 1348 (“The patentee is entitled to the full scope of his claims, and we will not limit him to his preferred embodiment or import a limitation from the specification into the claims.”). Despite what OBP would have the Court believe, the claims simply do not restrict the use or non-use of tools to facilitate detachment. For its part, as noted in the passage above, the specification teaches that fasteners can be used to facilitate a releasably attached illumination assembly. It is often the case in the mechanical arts that tools can be used with fasteners to attach and detach an



object, suggesting that where the claims are silent on the issue, they should not be construed to prohibit the use of tools. Similarly, there is nothing in the claim language that would require the detachment of the illumination assembly to occur without disassembly of the speculum. In fact, Figure 37 depicts a partially disassembled speculum that the patent describes as “a bottom perspective view of a portion of the vaginal speculum apparatus of FIG. 36, in particular representing the top blade of a disposable speculum **having an illuminator assembly releasably attached thereto.**” (’175 Patent, col. 6, lines 39-42 (emphasis added).) Clearly, the patent contemplates a releasably attached illumination assembly even where the speculum is partially disassembled. Thus, where the claims do not mention disassembly, a limitation directed toward disassembly should not be read into the claims. OBP’s construction should be rejected, and the Court should adopt the construction proposed by Welch Allyn.

#### VI. **“portable illumination assembly”**

Claim Term/Phrase	Proper Construction
“portable illumination assembly”  ( <i>Claims 1, 9, 18</i> )	A self-contained illumination assembly that is not connected to a non-portable power source, such as a cord or other tether to a power supply

Claim 1 requires that the claimed specula have:

a **portable illumination assembly** defined by a housing **that retains a portable power supply**, at least one LED and an integral curved light pipe made from a light transmissive material, said at least one LED being adjacent to and optically coupled to a proximal end of said integral curved light pipe . . . .

(Emphasis added.) Asserted Claims 9 and 18 commonly require that the claimed specula have “a **portable illumination assembly comprising a portable power source**, at least one LED, and a mechanism for energizing said at least one LED within a common housing . . . .” (Emphasis added.)

The claims themselves clearly define the portable illumination assembly as “retaining” or “comprising” a “**portable**” power supply, as opposed to using a cord or other tethered power supply that would make the power supply non-portable. Thus, the Court should construe this term to mean “a self-contained illumination assembly that is not connected to a non-portable power source, such as a cord or other tether to a power supply.” *See, e.g., Chimie*, 402 F.3d at 1377 (“Claim construction begins with the intrinsic evidence of record, looking first to the claim language itself to define the scope of the patented invention” and only if “the claim language itself lacks sufficient clarity to ascertain the scope of the claims, [do] we look to the written description for guidance”).

This construction is in accord with the teaching in the specification of the '175 Patent, in which the term “portable” is consistently used to refer to an illumination assembly that is cordless or un-tethered to a power source, in contrast to corded assemblies that require a non-portable power supply such as AC power. (*See, e.g., '175 Patent*, col. 2, lines 17-29 (“the use of **corded** illumination assemblies requires a **non-portable** (*e.g., AC*) power supply to be present in the examination area, making field examinations difficult.”) (emphasis added); col. 16, lines 6-13 (“Due to the **portable and non-tethered (cordless)** nature of the illumination assembly 230, FIG. 7, according to this and other described embodiments that follow, the herein described speculum apparatus 200 is more versatile . . . .”) (emphasis added); col. 9, lines 24-45 (“In one variation, the receiving cavity 217 of the speculum 204 can interchangeably receive either a **corded** illumination assembly 140, FIG. 1, and similarly constructed assemblies utilizing **a non-portable** power supply (*e.g., an AC power supply*) or a portable illumination assembly such as, for example, the exemplary assembly 230 more completely shown in FIGS. 8, 11 and 12.”) (emphasis added).)

OBP's construction ignores the distinction between portable and non-portable made in the claims and the specification, and instead attempts to import into the claims limitations that simply are not there. (*See* JCCS, Exhibit A, p. 8.) For example, there is nothing in the claims or the specification that would require the portable illumination assembly to be reusable. In fact, the opposite is true. As discussed above in the context of the proper construction of the "disposable" terms, both the claims and the specification allow for a fully disposable illumination assembly. (*See, e.g.*, Claim 12 ("An apparatus as recited in claim 9, wherein the entire apparatus is disposable"); '175 Patent, col. 4, lines 35-37 ("According to one version, the speculum is **disposable**, [a]lternatively, **the entire apparatus, including the illumination assembly, is disposable**.")) (emphasis added).)

Similarly, there is nothing about the term "portable illumination assembly" that requires the assembly to be attachable or detachable from the speculum. Other claim terms, such as the term "releasably attached" discussed above, are directed to that issue. Thus, OBP's attempt to import into the term "portable illumination assembly" a requirement that it be "attachable and detachable from a speculum without undue effort, disassembly or breakage" would improperly render terms like "releasably attached" redundant and unnecessary.<sup>4</sup> *See, e.g., John Mezzalingua Assocs. v. Corning Gilbert Inc.*, No. 5:11-cv-761 (GLS/DEP), 2012 U.S. Dist. LEXIS 166275, \*31-\*32 (N.D.N.Y. Nov. 21, 2012) (rejecting construction of a term where the proposed "additional constraints echo limitations contained elsewhere within the claims of those patents

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<sup>4</sup> OBP's construction further begs the questions of what would and would not be considered "undue effort" and "disassembly or breakage?" That is to say, OBP's construction is confusing and ambiguous and thus itself would require construction by the Court for the jury to understand what it means, which is reason enough to reject it. *See Augme Techs., Inc. v. Yahoo!, Inc.*, 09 05386, 2012 U.S. Dist. LEXIS 151, \*74 (N.D. Cal. Jan. 3, 2012) (rejecting proposed construction that would insert phrases requiring further construction); *Stanacard, LLC v. Rebtel Networks*, AB, 680 F. Supp. 2d 483, 493 (S.D.N.Y. 2010) (rejecting proposed construction that only introduced additional terms into the claim and would result in jury confusion).

and would render those additional limitations redundant if imported into the definition” of a different term). Further, the claims do not speak to the issue of disassembly or the level of effort required to detach the portable illumination assembly. OBP is simply making those limitations up, which is improper. Finally, there is nothing in the claims that would require that the portable illumination assembly be capable of use as a “stand-alone examination light.” While there are exemplary embodiments in the specification in which the illumination assembly can be used that way, the claims certainly do not require it. OBP’s construction is the epitome of the “cardinal sin” of claim construction. OBP is importing limitations from the specification into the claims, and its construction should be rejected. *See, e.g., Kara Tech*, 582 F.3d at 1348 (“The patentee is entitled to the full scope of his claims, and we will not limit him to his preferred embodiment or import a limitation from the specification into the claims.”); *Teleflex*, 299 F.3d. at 1324 (holding that it is a “cardinal sin” to import limitations from the specifications into the claim).

## VII. Indefiniteness

In *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120 (2014), the United States Supreme Court held that claims need only be **reasonably certain** to be definite; they do not have to be absolutely precise or certain. *Id.* at 2129 (“recognizing that absolute precision is unattainable”). “[T]he certainty which the law requires in patents is not greater than is reasonable, having regard to their subject-matter.” *Id.* “Some modicum of uncertainty, the Court has recognized, is the ‘price of ensuring the appropriate incentives for innovation.’” *Id.* at 2128 (quoting *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 732 (2002)). The Court also reaffirmed that **definiteness is viewed exclusively from the standpoint of a person of ordinary skill in the relevant art**, and patent claims are presumed definite and valid. *See id.* To overcome this presumption, an accused infringer (in this case, OBP) has the **burden to prove by clear and convincing evidence** that a person of ordinary skill at the time the patent was filed

would have viewed the claim(s) as indefinite. *See Haemonetics Corp. v. Baxter Healthcare Corp. at al.*, 607 F.3d 776, 783 (Fed. Cir. 2010); *Haliburton Energy Servs., Inc. v. M I LLC*, 514 F.3d 1244, 1249-50 (Fed. Cir. 2008). In *Nautilus*, the Court expressly declined to revisit the applicability of the clear and convincing evidence standard to definiteness challenges. *See* 134 S. Ct. at 2130 n.10. Therefore, it remains the law. *See id.*; *In re Maxim Integrated Prods., Inc.*, MDL 2354, 2014 U.S. Dist. LEXIS 100448, \*44-\*56 (W.D. Pa. July 23, 2014).

In this case, OBP has suggested that it may argue that a number of terms in the asserted claims are “indefinite.” (*See* JCCS, Exhibit A, pp. 3-4.) However, OBP has not explained how or why such terms are indefinite, nor has it disclosed any actual evidence that it intends to use to meet its burden of proof.<sup>5</sup> Thus, Welch Allyn does not know what OBP’s arguments are, or whether there are disputed issues of material fact concerning the factual issues that are subsidiary to the ultimate issue of definiteness, precluding a finding of indefiniteness at this early stage of the proceedings. As such, Welch Allyn will address in its Responsive Claim Construction Brief any “indefiniteness” arguments that OBP explains in its opening claim construction brief, as well as provide any evidence needed to show that the claims are definite.

### **Conclusion**

Welch Allyn respectfully requests that the Court construe the disputed terms of the ’175 Patent as set forth herein.

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<sup>5</sup> The report of Karl Leinsing that OBP served with its claim construction disclosures is hardly evidence of anything. That report, replete with case law cites and legal argument, was obviously penned by OBP’s lawyers. It is nothing more than inadmissible attorney argument ratified by Mr. Leinsing in exchange for a fee. Moreover, in the few instances when the report even bothers to address indefiniteness, an issue for which OBP bears the burden of proof, it offers little more than bald conclusions without any real analysis for why the claim scope would not have been reasonably certain to a person of ordinary skill in the art at the time of the invention.

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**CERTIFICATE OF SERVICE**

I certify that on May 28, 2015, I filed a copy of the foregoing document, Welch Allyn, Inc.'s Opening Claim Construction Brief, as well as the accompanying documents, with the Clerk of the Court via the CM/ECF system, which gave notice to all counsel who have made an appearance in this action.

/s/ Bella S. Satra

Bella S. Satra